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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,749	03/30/2004	Dominique Charmot	ILPS 04031.101	7226

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
08/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/814,749	CHARMOT ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,14,15,18-22,29,30,34,36,40 and 51-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *3,4,14,15,18-22,29,30,34,36,40 and 51-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/6/06; 11/16/06; 3/22/07; 4/6/07; 4/25/07; 6/7/07; 6/11/07; 6/22/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement dated: 11/06/06, 11/16/06, 3/22/07, 4/06/07, 4/25/07, 6/07/07, 6/11/07, 6/22/07.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating human patients suffering from renal disorders such as renal failure, insufficiency and end stage renal disease or hyperkalemia, does not reasonably provide enablement for treating any animal subject of an indeterminate disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (A) The breadth of the claims; The claims are drawn to the treatment of all animals for any possible disorder or disease. The population for this claim includes the entirety of the known and unknown animal kingdom. There would no way to determine the effected population that would need the treatment method of the instant claims. The specification is only enabled for the treatment of a humans. No other animals are provided with treatment methods. Applicant has

claimed a treatment method for the every possible animal known and unknown at the current time, for indeterminate number of diseases or disorders. (B) The nature of the invention; the rejected claims are drawn to solid particulate formulations and methods of use so the nature of the invention is pharmaceutical. (C) The state of the prior art; The current state of the art has well established methods of treating specific diseases and disorders. However a disease or disorder must by matched to the treatment method. Further only a specific population will respond to the treatment method. However the claims do not provide a disorder or population. (D) The level of one of ordinary skill; The level of skill in the art would be a Board certified pharmacists or PhD with several years of experience (E) The level of predictability in the art; Despite advances medical science has been unable to find a single compound that works for very single instance to justify a preventative nature. In such cases it is proper for the USPTO to required evidence that such an unprecedented accomplishment has been accomplished *In re Feren*, 163 USPQ 609. No such evidence has been provided . The failure of skilled artisan scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genetech vs. Novo Nordisk*, 42 USPQ 2nd 1001, 1006. That is, the skill is so low that no compound effective generally against disorders has ever been found let alone one that can prevent such conditions. (F) The amount of direction provided by the inventor; Applicant provided direction to administer the core/shell particles to humans. No information about any other animal is provided. Nor any treat, nor prevent mite infections in honeybee and not in the entire insect kingdom. (G) The existence of working examples; the working examples provide methods of making the core/shell particles and a method of administering the compound to humans. No other animals are discussed and no other disorders

other than renal disorders are discussed. (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. The pharmacist or practicing diagnostician would need to find a way to locate catalogue and identify every possible animal in the world As discussed above the highly skilled entomologists would be required to determine criteria to establish which populations were susceptible to every infection, next test every possible known species of animal for every possible disease and later try the compound on each animal.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 3,4,14,15,18-22,29,51-75 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardon et al (USPN 3,874,907 hereafter '907). The claims are drawn to a microparticle comprising a core and a shell where the shell is a crosslinked polymer ethylenic, vinylic methacrylic and acrylic monomers, while the core polymer includes a cation exchange polymer comprising functional groups such as carboxylate, phosphate, sulfate, sulfonate, sulfamate and combinations thereof.

3. The '907 patent teaches as microparticle formulation comprising cationic exchange polymers (abstract). The microcapsules comprise a core and coating where the core comprises a cationic polymer such as sulphonic acid resin with a diameter between 100-2000 microns and a

shell with a thickness between 1-50 microns (col. 12, lin. 44-60, example 1). As a ratio of shell thickness to core diameter this is 0.01:1-0.2:1 meeting the limitation of the claims. The shell polymers include crosslinked polymers of vinylic, methacrylic and ethylenic monomers (col. 6, lin. 63-68). The polymers of the shell are hydrophobic (col. 6, lin. 5-10).

4. Regarding the potassium binding (percentage of ions, selection of ion, etc.) limitations, it is the position of the Examiner that these limitations are inherently met by the '907 patent. The '907 patent provides microparticles with a core/shell morphology with the same polymers in the shell and core as those of the instant claims. The shells/skins and cores of the '907 patent are identical to those of the current claims. The cores comprise sulphonated acid resins while the shell/skin comprise polymerized vinyl, ethylenic or methacrylic monomers. These polymers arranged in the same way as the instant claims and exchange polymers of the surrounding environment (col. 14, lin. 12-26). For these reasons the it is the position of the Examiner that the microparticles would inherently pass through the intestine without disintegrating, and bind at least 75% of the surrounding potassium, and remove the ions from the intestinal system inherently.

5. Regarding the removal of the potassium ions from the intestinal tract of the a human patient suffering from various kidney disorders, it is the position of the Examiner that such limitations are merely a future intended use and do not impart patentability on the products claimed. The products are identical to those of the prior art. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

6. Regarding product claims reciting the production of the polymer shells, it is the position of the Examiner that such limitations do not impart patentability on the claims since they are merely product by process claims.

7. For these reasons at least the claims are anticipated by the '907 patent.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 30 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Gardon et al (USPN 3,874,907 hereafter '907) in view of Warchol et al (USPN 5,413,782 hereafter '782). The claims are drawn to a pharmaceutical composition comprising a microparticle, wherein the microparticle comprises a core, shell and an additional enteric coating.

11. As discussed above the '907 patent discloses a core/shell particle where the core is a cation-exchange polymer and the shell is a hydrophobic polymer comprising vinyl, methacrylate or ethylenic polymers. The reference is silent to an additional enteric coating, however the addition of an enteric coating in order to increase the stability of the microparticle is well know in the art as seen in the '782 patent.

12. The '782 patent discloses a coated ion exchange particle formulation (abstract). The ion exchange polymers include polymers having monomer units of styrene, divinylbenzene, acrylic acid and acrylamide (col. 6, lin. 48-61). The particles are sized from 10-2000 microns (col. 7, lin. 1-5). The particles are enterically coated in order to ensure stability while passing through the digestive system (col. 5, lin. 35-40). These polymers include known enteric polymers such as cellulose acetates and acrylics (col. 9, lin. 30-40). A skilled artisan would have been motivated to include this enteric coating on to the particles of the '907 patent in order to improve the stability of the particles in more acidic environments.

13. Regarding the treatment of hyperkalemia, since the core/shell particles of the '907 patent would inherently remove potassium ions from the environment they would be useful in treating hyperkalemia and thus reducing the potassium in the body. The coating of the '782 would make the particles of the '907 stable for intestinal delivery and the core/shell particles would inherently bind the potassium and carry the excess ions out of the body.

14. One of ordinary skill in the art would have been obvious to coat the particles of the '907 patent with the enteric polymers shown in the '782 patent since both comprise similar cores of cationic exchange polymers. The skilled artisan would have been motivated to combine the coat the particles of the '907 patent in order to improve their stability in acidic environments.

Response to Arguments

15. Applicant's arguments with respect to claims 3,4,14,15,18-22,29,30,34,36,40,51-75 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

1. Claims 3,4,14,15,18-22,29,30,34,36,40, and 51-75 of this application conflict with claims 1,10,16,17,20-24,31,32,45-65 of Applicant No. 10/813,872. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

2. Claims 3,4,14,15,18-22,29,30,34,36,40, and 51-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,10,16,17,20-24,31,32,45-65 of copending Application No. 10/813,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite pharmaceutical formulations comprising core-shell formulation comprising potassium-binding polymers that are crosslinked. The formulations both have shells with thicknesses up to 50 microns. These claims would act as obviating art over each other.

3. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER